



PATHWAY
MEDICAL TECHNOLOGIES

5100462

MAY 19 2010

510(k) SUMMARY

General Information:

Date of Summary Preparation: February 17, 2010

Name and Address of Manufacturer: Pathway Medical Technologies, Inc.
10801 120th Ave NE
Kirkland, Washington 98033

Contact Person: Brit Baird
Regulatory Affairs Specialist
Phone: 425-636-4137
Fax: 425-636-4001

Trade Name: Jetstream G3TM L System
Jetstream G3TM System

Common Name: Peripheral Atherectomy Catheter

Regulation Number: 21 CFR 870.4875

Regulation Name: Intraluminal Artery Stripper

Regulatory Class: Class II

Classification Panel: Cardiovascular

Product Code: MCW

Predicate Devices: Manufacturer: Pathway Medical Technologies, Inc.
(1) Jetstream G3TM L System (K093918)
(2) Jetstream G3TM System (K093456)
(3) JetstreamTM Pathway PVTM Atherectomy System
(K083489)
(4) Pathway PVTM Atherectomy System (K081328)

Indications for Use

The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Device Description

The Jetstream G3 L and the Jetstream G3 Systems are designed to provide atherectomy and thrombus removal treatment with similar performance requirements. Both are designed with an expandable cutting tip and infusion and aspiration functions intended for use in debulking and treating vascular disease in the peripheral vasculature. These functions allow for the active removal of fluid, excised tissue, and thrombus from the peripheral treatment site.

The Jetstream G3 L and the Jetstream G3 Systems thus retain the same two primary components: a Catheter with Control Pod and a Console. These two system components are packaged separately and described generally below.

- **Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically-driven Catheter with attached Control Pod. The Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities and the Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double pouched tray.
- **PV Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

Substantial Equivalence

Information was provided to demonstrate that the Jetstream G3 L and the Jetstream G3 Systems with the modified indications for use are substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 19 2010

Pathway Medical Technologies, Inc.
c/o Mr. Brit Baird
Regulatory Affairs Specialist
10801 120th Ave NE
Kirkland, WA 98033

Re: K100462
Trade Name: Jetstream G3 L System and Jetstream G3 System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: April 12, 2010
Received: April 13, 2010

Dear Mr. Baird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

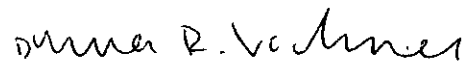
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K100462

Device Names: Jetstream G3™ System;
Jetstream G3™ L System

Indications for Use:

The Jetstream System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

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